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10/783,897

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EXAMINER

VU, QUYNH-NHU HOANG

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JOHN T. SANTINI, JR., MICHAEL J. CIMA, and
ROBERT S. LANGER

Appeal 2009-008830
Application 10/783,897
Technology Center 3700

Before: LINDA E. HORNER, WILLIAM F. PATE III, and
FRED A. SILVERBERG, *Administrative Patent Judges*.

PATE III, *Administrative Patent Judge*.

DECISION ON APPEAL¹

¹ The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the “MAIL DATE” (paper delivery mode) or the “NOTIFICATION DATE” (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

STATEMENT OF CASE

Appellants appeal under 35 U.S.C. § 134 from a rejection of claims 55-103. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm-in-part.

The claims are directed to a medical device with a controlled reservoir opening. Claim 55, reproduced below, is illustrative of the claimed subject matter:

55. An implantable medical device for the controlled release of drug molecules comprising:
a substrate;
at least two reservoirs in the substrate;
release system disposed in the reservoirs, the release system comprising drug molecules for release; and
discrete metal reservoir caps positioned over or within openings in the reservoirs,
wherein release of the drug molecules from the device is activated by disintegration of the reservoir cap and the disintegration of the reservoir cap is actively controlled.

REFERENCES

The prior art relied upon by the Examiner in rejecting the claims on appeal is:

Auborn	US 3,891,457	Jun. 24, 1975
Sapru	US 4,623,597	Nov. 18, 1986
Currie	US 5,366,454	Nov. 22, 1994
Miyazaki	US 6,537,938	Mar. 25, 2003

REJECTIONS

Claims 77-84, 86-93, and 95-103 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Currie. Ans. 3.

Claims 55-76, 85 and 94 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Currie. Ans. 4.

A rejection of claims 58 and 61 under 35 U.S.C. § 112, first paragraph, has been withdrawn by the Examiner. Ans. 2.

OPINION

We have carefully reviewed the rejections on appeal in light of the arguments of the Appellants and the Examiner. As a result of this review, we have reached the determination that claims 55-76, 85, 94, and 97-102 do not lack novelty and are not obvious over applied the prior art. On the other hand, we find that claims 77-84, 86-93, 95, 96 and 103 do lack novelty or are prima facie obvious over the prior art cited by the Examiner. Therefore the rejections of this second group of claims will be affirmed. Our reasons follow.

As an initial matter, we will construe the claim term “disintegration” or “disintegrating” as it appears in the independent claims on appeal. Although Appellants have provided examples of disintegration in the Specification, Appellants have not defined the term. *See, e.g.*, Spec. 4:1-7; 8:2-8. Therefore, in construing the claims on appeal, we will apply the ordinary and customary meaning of the term “disintegration.” A dictionary definition of disintegration is “to separate into parts or lose intactness or solidness; break up; deteriorate.” RANDOM HOUSE DICTIONARY OF THE ENGLISH LANGUAGE 566 (2d Unabridged ed. 1988).

Turning to the Currie reference, Currie discloses a substrate or body 12 having multiple reservoirs 16 disposed therein in which a medicine is stored. The reservoir has a delivery opening 20 covered by a reservoir cap or membrane 24 constructed of silicon. *See* col. 5, ll. 37-52. When the implantable device of Currie is constructed, the membrane 24 is placed on

the opening 20 in a pre-stressed condition. *See* col. 6, ll. 11-15, fig. 9. Transducers 26a and 26b are provided to place additional stress on membrane 24 and to break it into fragments. *See* col. 6, l. 66-col. 7, l. 5. In our view, the destruction of membrane 24 and breaking the membrane into fragments is disintegration of the membrane. It certainly satisfies the definition of “break down” or “loss of solidness or intactness.” Claims 77 and 91 are independent claims that merely require disintegration of the reservoir caps for the dispensing of the drug. As noted above, we find that Currie disintegrates the membrane 24. Accordingly, we affirm the 35 U.S.C. § 102 rejection of independent claims 77 and 91 along with claims 78-84, 86-90, 92, 93, 95, 96, and 103, dependent claims not separately argued. For the reasons provided below, we do not affirm the 35 U.S.C. § 102 rejection of claims 97-102 as these claims are separately argued.

We reverse the 35 U.S.C. § 103 rejections of claims 55-76, 85 and 94 for the following reasons. Independent claim 55 requires the reservoir caps to be metal. Currie neither discloses metal reservoir caps, nor would Currie render the provision of metal caps *prima facie* obvious. Claims 85 and 94 are also directed to metal caps. Therefore the 35 U.S.C. § 103 rejection of claims 55-68, 85, and 94 are reversed.

Claim 69 requires electrical conductivity through the reservoir cap and states that the disintegration of the reservoir cap is due to direct application of an electrical potential through the reservoir cap. In Currie, while potential is provided to the piezoelectric transducers, 26a and 26b, no current is provided through the membrane 24 which is a pre-stressed silicon unit. In short, the disintegration of the membrane 24 in Currie is due to a mechanical force provided by the transducers. This is distinct from the

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electrical potential claimed in claim 69, as Appellants argue. Accordingly, we reverse the 35 U.S.C. § 103 rejection of claims 69-76.

Separately argued independent claim 97, rejected under 35 U.S.C. § 102, requires that the cap disintegrate by dissolving into solution or by forming soluble ions or oxidation compounds. Thus claim 97 is directed to disintegration of the reservoir cap by an electrochemical mechanism. We agree with Appellants that the reference Currie disintegrates the cap by an electromechanical shear stress provided by the transducers 26a and 26b. Therefore, claims 97-102 do not lack novelty over the reference to Currie.

We have carefully considered the references to Auburn, Sapru, and Miyazaki that the Examiner cited but did not apply in the statement of the rejection. We find nothing therein that would have persuaded us that the electrochemical reaction required by Appellants is inherent in Currie or that it is obvious from the disclosure of Currie and Auburn or Sapru. Additionally, the fact that a silicon material is an anode in the Miyazaki disclosure does not establish that the cap of Currie functions as an anode. It does not.

Furthermore, we must note where a reference is relied on to support a rejection, whether or not in a “minor capacity,” there would appear to be no excuse for not positively including the reference in the statement of the rejection. *In re Hoch*, 428 F.2d 1341, 1342 n.3 (CCPA 1970).

DECISION

For the reasons given above, the Examiner’s decision to reject claims 55-76, 85, 94, and 97-102 is reversed.

The Examiner’s decision to reject claims 77-84, 86-93, 95, 96 and 103 is affirmed.

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No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv) (2009).

AFFIRMED-IN-PART

nlk

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